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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,588	10/15/2002	Leszek Wojnowski	VOS-31	7619

7590

04/08/2005

James F Haley Jr  
Fish & Neave  
1251 Avenue of the Americas  
New York, NY 10020-1104

EXAMINER

CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/070,588	Applicant(s) WOJNOWSKI ET AL.	
	Examiner Gyan Chandra	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-33 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☒ Claim(s) 6-8 and 36-37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/8/2002</u> . | 6) <input type="checkbox"/> Other: _____  |

101

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group 30, claims 1-8, 34, and 36-37 in the reply filed on 02/23/2005 is acknowledged.

### **Status of Application, Amendments, And/Or Claims**

Claims 1-37 are pending. The amendment of claims 1, 34, and 36, and the withdrawal of claims 9-33, and 35 are acknowledged.

Claims 1-8, 34, 36 and 37 are under examination.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 32). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Objections***

Claims 3-8, and 36-37 are objected to under 37 CFR 1.75(c) as being in improper form because of multiple dependent claims 3-8, and 36-37. See MPEP § 608.01(n). Claims 3-8, and 36-37 refer alternative to more than one claim (for example, claim 3 refers to claim 1 or 2; claim 4 refers to claims 1-3; claim 5 refers to

claim 4 which refers to claims 1-3). Accordingly, the claims 3-8, and 36-37 have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a polynucleotide that encodes a variant hPXR protein or fragment thereof. The claim does not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or any other disclosed distinguished feature. Thus the claims are drawn to a genus of nucleic acids that is defined solely by sequence identity.

To provide undisclosed possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics for the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of

making the chemical product, or any combination thereof. There is not even identification of any particular portion of the structure that must be conserved. Further, the recited activity of a hPXR variant as the activation by rifampicin (page 36-37) is not specific because specification does not disclose any significant effect on variants. Also, specification does not suggest what activity to correlate with any variant. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly &*

Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states an adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolating it. The compound itself is required. See Fiers v. Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen v. Baird, 30 Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 148 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provides only the bovine sequence. Therefore, only the isolated polynucleotide comprising the amino acid sequence set forth in SEQ ID NO: 112, but not the breadth of the claims meet the written description provision of 35 U.S.C. § 112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hwang et al (Genomics 30: 293298, 1995; Accession R57583, GI: 827441).

Hwang et al teach a polynucleotide sequence GI: 827441 expressed in a human fetal heart library which is 100% identical to the polynucleotide sequence of SEQ ID NO: 112 of the instant application (see appendix –A for the sequence alignment).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Mittman et al ( U S Patent No. 6821724).

Mittman et al teach a polynucleotide sequence of SEQ ID NO: 49096 from nucleotide 9-19 which is 100% identical to the nucleic acid sequence of SEQ ID NO:

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112 (see the sequence alignment, Appendix B). They teach use of nucleic acid for medical diagnosis (column 1, line 30).

***Conclusion***

No claim is allowed.




Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra  
AU 1646  
28 March 2005

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

# Appendix - A

RESULT 28  
 R57383/c 150 bp mRNA linear EST 02-MAY-1996  
 LOCUS F2971 Fetal heart Homo sapiens cDNA clone F2971 5' end, mRNA  
 DEFINITION sequence.  
 R57383  
 ACCESSION R57383.1 GI:827441  
 VERSION  
 KEYWORDS EST.  
 SOURCE Homo sapiens (human)  
 ORGANISM Homo sapiens  
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;  
 Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.  
 REFERENCE 1 (bases 1 to 150)

AUTHORS Hwang,D.M., Fung,Y.W., Wang,R.X., Laurensen,C.M., Ng,S.H.,  
 Lam,W.Y., Tsui,K.W., Fung,K.P., Waye,M., Lee,C.Y. and Liew,C.C.  
 TITLE Analysis of expressed sequence tags from a fetal human heart cDNA  
 library  
 JOURNAL Genomics 30 (2), 293-298 (1995)  
 MEDLINE 96163883  
 PUBMED 8586430  
 COMMENT Contact: Liew CC  
 Brigham and Women's Hospital  
 Harvard Medical School  
 75 Francis St. Boston, MA 02115, USA  
 Tel: 6177328915  
 Fax: 6179750995  
 Email: cliew@rics.bwh.harvard.edu  
 Seq primer: GGTGGCGACGACTCCTGGAGCC.  
 FEATURES Location/Qualifiers  
 source 1..150  
 /organism="Homo sapiens"  
 /mol\_type="mRNA"  
 /db\_xref="taxon:9606"  
 /clone="F2971"  
 /lab\_host="E. coli Y1090"  
 /clone\_lib="Fetal heart"  
 /note="Vector: Lambda gt22; Site 1: NotI; Site 2: SalI;  
 mRNA was purified from human fetal hearts (10-12 weeks).  
 cDNA was constructed using a NotI-Oligo dT adaptor-primer.  
 SalI adaptors were ligated, followed by digestion with  
 NotI, for direction cloning into predigested lambda gt22.  
 Method is described in J. Mol. Cell. Cardiol. (1994) 26,  
 1329-1333)"

ORIGIN  
 Query Match 100.0%; Score 11; DB 7; Length 150;  
 Best Local Similarity 100.0%; Pred. No. 1.7e+04;  
 Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 CTTTGGCACTA 11  
 |||||  
 Db 48 CTTTGGCACTA 38

## Appendix - B

```
RESULT 1
US-09-396-196G-49096
; Sequence 49096, Application US/09396196G
; Patent No. 6821724
; GENERAL INFORMATION:
; APPLICANT: Michael Mittmann
; APPLICANT: David Mack
; APPLICANT: David Lockhart
; APPLICANT: Affymetrix, Inc.
; TITLE OF INVENTION: Methods of Genetic Analysis
; FILE REFERENCE: 3101.1
; CURRENT APPLICATION NUMBER: US/09/396,196G
; CURRENT FILING DATE: 1999-09-15
; PRIOR APPLICATION NUMBER: 60/100,678
; PRIOR FILING DATE: 1998-09-17
; NUMBER OF SEQ ID NOS: 127806
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 49096
; LENGTH: 25
; TYPE: DNA
; ORGANISM: mus musculus
US-09-396-196G-49096

Query Match          100.0%; Score 11; DB 4; Length 25;
Best Local Similarity 100.0%; Pred. No. 5.2e+02;
Matches 11; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY          1 CTTTGGCACTA 11
             |||||
Db          9 CTTTGGCACTA 19
```